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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,328	12/04/2001	Preeti Lal	PF-0709 USN	6996

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 08/18/2003 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,328	LAL ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,15-17,19,22,26,27 and 231* is/are pending in the application.

4a) Of the above claim(s) *8,10,13,15,27 and 231* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,11,16,17,19,22 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Inventions 37, 75, and 304 (Claims 1-7, 9, 11, 16, 17, 19, 22, and 26 drawn to polypeptide having SEQ ID NO: 41 and polynucleotide SEQ ID NO: 84) as agreed upon in the Telephonic Interview held June 4, 2003 (Paper #10) in Paper No. 11, filed June 17, 2003 is acknowledged. The traversal is on the ground(s) that it would be minimal additional burden on the Examiner if the antibodies against SEQ ID NO: 41 were also examined. This is not found persuasive because the search of the antibodies and issues surrounding the antibodies regarding enablement and art are wholly different from those of the polypeptide and encoding nucleic acid. Further, the antibody is a product onto itself, differing in structure and in activity from the polypeptide and nucleic acid, as pointed out in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Applicants have requested that upon allowance of the protein claims, that the Examiner reconsider rejoinder of the antibodies. Rejoinder is generally governed by In re Ochiae, wherein the methods of using the allowed product are rejoined with the allowed product, contingent that the methods utilize the product as allowed.

Claims 1-11, 13, 15-17, 19, 22, 26, 27, and 231 are currently pending. Claims 8, 10, 13, 15, and 231 have been withdrawn from further consideration by the Examiner because these are drawn to non-elected inventions. Claims 1-7, 9, 11, 16, 17, 19, 22, and 26, as they are drawn to SEQ ID NO: 41 or NO: 84, are under examination.

Priority date is June 17, 1999.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See the hyperlink at page 20, line 25 and 29, for example. All hyperlinks are required to be deleted.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9, 11, 16, 17, 19, 22, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7, 9, 11, 16, 17, 19, 22, and 26 contain non-elected subject matter and therefore do not particularly point out and distinctly claim the subject matter of the elected invention.

In Claim 1, it is not clear what activity the biologically active fragment will have.

In Claim 1, it is not clear what type of antibody an immunogenic fragment will have.

In Claims 19, 22, and 26, it is not clear what activity is being assessed.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, 9, 11, 16, 17, 19, 22, and 26 rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Throughout the specification, the polypeptide having the amino acid sequence SEQ ID NO: 41 is stated to be a human transport protein, or TPPT-41 (page 10, line 34). The specification presents cloned DNA and the polypeptide sequence is deduced therefrom. Prophetic expressions systems are discussed at pages 70-71. A prophetic assay to demonstrate TPPT activity is discussed at page 71-72. No polypeptide having SEQ ID NO: 41 is in

hand, and no assay determining its activity has been done. In Table 2 at page 87, the polypeptide having SEQ ID NO: 41 is stated to be homologous to myelin protein zero.

Goddard et al. (Pre-grant Pub US 2002/0192752) have in hand polypeptide PRO7425 having their designated SEQ ID NO: 12 which is identical to instant SEQ ID NO: 41. In Example 5, Goddard et al. demonstrate that PRO7425 stimulates the proliferation of T-lymphocytes 313% over CD4-IGG simulated control. Thus, while the instant specification discloses TPPT-41 as an intracellular transport protein based on deduced amino acid sequence homology to other transport proteins, the prior art teaches that this same protein is a extracellular-acting cytokine that stimulates the proliferation of T-cells.

Therefore, the instant invention lacks utility because the polypeptide TPPT-41, variants having 90% identity to SEQ ID NO: 41, biologically active and immunogenic active fragments thereof has been disclosed to be a transport protein or derived therefrom when this same protein has actually been shown to stimulate T lymphocyte proliferation. Thus, one skilled in the art could not use the polypeptide as disclosed. The polynucleotide encoding TPPT-41and polynucleotides having at least 70% identity to SEQ ID NO: 84 also lacks utility because the polynucleotide has been taught to encode a transport protein. Further, the methods of using TPPT-41 for screening agonists, antagonists, or compounds that alter its activity lack utility because one could not perform the methods using the end-result disclosed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9, 11, 16, 17, 19, 22, and 26 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific, or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1, 3, 6, 7, 9, 11, 16, 19, 22, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 11 recite percent identities. The specification does not describe a functional polypeptide fragments or polypeptides having at least 90% identity to SEQ ID NO: 41, or a polypeptide having at least 70% identity to SEQ ID NO: 84 and having function. Therefore, the specification lacks written description for these variants.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 11, 16, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Goddard et al. (Pre-grant Pub US 2002/0192752, priority to September 9, 1998). Goddard et al. teach polypeptide PRO7425 having their designated SEQ ID NO: 12 which is identical to instant

SEQ ID NO: 41. Therefore, Goddard et al. teach a polypeptide comprising SEQ ID NO: 1 (Claim 1a), having at least 90% identity to SEQ ID NO: 41 (Claim 1b), comprising a biologically active fragment of SEQ ID NO: 41 (Claim 1c), and comprising an immunogenic fragment of SEQ ID NO: 41 (Claim 1d). The PRO7425 is the same length as SEQ ID NO: 41; therefore, PRO7425 is a polypeptide that consists of SEQ ID NO: 41 (Claim 2). In Example 5, Goddard et al. demonstrate that PRO7425 stimulates the proliferation of T-lymphocytes 313% over CD4-IGG simulated control; thus, PRO7425 was placed in a pharmaceutical composition to perform this assay (Claims 16, 17)

SEQ ID NO: 11 of Goddard et al. encodes PRO7425 (Claims 3, 4). SEQ ID NO: 11 shares 99.9% identity to instant SEQ ID NO: 84 and therefore shares at least 70% identity to SEQ ID NO: 84 (Claim 11). The complements of SEQ ID NO: 11 (page 5, right col., para. 0057) and RNA encoding SEQ ID NO: 41 are included in the definition of polynucleotide (page 9, right col., para. 0091)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-7, 9, 19, 22, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goddard et al. (Pre-grant Pub US 2002/0192752, priority to September 9, 1998).

SEQ ID NO: 11 of Goddard et al. encodes PRO7425 (Claim 4). SEQ ID NO: 11 shares 99.9% identity to instant SEQ ID NO: 84 and differs from SEQ ID NO: 84 by lacking the 3'C that is not involved in the coding or expression of PRO7425. Therefore, a polynucleotide consisting of SEQ ID NO: 84 is an obvious variant of SEQ ID NO: 11 disclosed by Goddard et al. because the 3' C does not contribute to the coding or expression of PRO7425 (Claim 5).

At Example 4, Goddard et al. notes that the clone from which PRO7425 is made has been deposited. Indeed, in Example 5, Goddard et al. demonstrate the activity of PRO7425 and therefore Goddard et al. must have recombinantly produced PRO7425 though Goddard et al. does not expressly teach how the PRO7425 was recombinantly produced. Goddard et al. provides many examples for the recombinant production of PRO polypeptides. The expression of PRO polypeptides in E. coli is discussed in Example 9, in mammalian cells in Example 10, in yeast in Example 11, and in insect cells in Example 12. After each of these examples, Goddard et al. states that "many of the PRO polypeptides disclosed herein were successfully expressed as described above". Therefore, Example 10 will be used to exemplify the expression of PRO7425. In Example 10, Goddard et al. suggest that PRO polypeptides can be expressed in mammalian cells such as CHO cells. Goddard et al. suggests to place DNA encoding PRO polypeptides into expression vector PRK5 and transfect CHO cells with this vector. The cultures are incubated and the conditioned medium harvested and the expressed PRO concentrated and purified. Therefore, it would have been obvious to a person having ordinary skill in the art to place the nucleic acid having SEQ ID NO: 11 in to the expression vector PRK5 (Claim 6) and transfect CHO cells with this vector (Claim 7) and culture the CHO cells to express PRO7425 and harvest PRO7425 from the conditioned medium and purified the PRO7425 therefrom (Claim 9) because Goddard et al. suggest that these vectors, host cells, and methods of recombinant production are useful for the expression of PRO polypeptides including PRO7425. This recombinant technique for producing PRO7425 is predictable because Goddard et al. state that many of the PRO polypeptides disclosed herein were successfully expressed using this method.

At page 6, left column, para. 0064, Goddard et al. teach methods for identifying agonists and antagonists to a PRO polypeptide which comprises contacting the PRO polypeptide with a candidate molecule and monitor a PRO mediated biological activity. The agonist or antagonist would be useful in the preparation of a medicament for a condition that is responsive to PRO

polypeptides (Page 6, top right col.). In Example 5, Goddard et al. teach a method fro stimulating T lymphocyte proliferation using PRO7425. Therefore, it would have been obvious to a person having ordinary skill in the art to perform a method for screening a compound for effectiveness as an agonist of PRO7425, said method comprising exposing a same comprising PRO7425 to the compound and determining an increase in T lymphocyte proliferation because Goddard et al. teach that this method would be useful for identifying agonists for the preparation of a medicament in the treatment of a condition responsive to PRO7425 (Claim 19, 26). It would have been obvious to a person having ordinary skill in the art to perform a method for screening a compound for effectiveness as an antagonist of PRO7425, said method comprising exposing a same comprising PRO7425 to the compound and determining a decrease in T lymphocyte proliferation because Goddard et al. teach that this method would be useful for identifying antagonists for the preparation of a medicament in the treatment of a condition responsive to PRO7425 (Claim 22, 26).

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Karen Cochrane Carlson Ph.D.

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August 15, 2003

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER